

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BARDY DIAGNOSTICS, INC.,

Plaintiff,

v.

IRHYTHM TECHNOLOGIES, INC.,

Defendant.

C.A. No. 24-1355-JDW

JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT

Plaintiff, Bardy Diagnostics, Inc. (“Bardy”) files this complaint against Defendant iRhythm Technologies, Inc. (“iRhythm”), seeking damages and other relief for patent infringement, alleging as follows:

Nature of the Action

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising out of iRhythm’s infringement of U.S. Patent No. 12,161,473 (the “’473 Patent”), U.S. Patent No. 12,171,562 (the “’562 Patent”), U.S. Patent No. 12,285,261 (the “’261 Patent”), and U.S. Patent No. 12,310,735 (the “’735 Patent”) (collectively, the “Asserted Patents”).

2. Bardy is the owner by assignment of the ’473 Patent. A copy of the ’473 Patent is attached as Exhibit 1.

3. Bardy is the owner by assignment of the ’562 Patent. A copy of the ’562 Patent is attached as Exhibit 2.

4. Bardy is the owner by assignment of the ’261 Patent. A copy of the ’261 Patent is attached as Exhibit 16.

5. Bardy is the owner by assignment of the '735 Patent. A copy of the '735 Patent is attached as Exhibit 17.

The Parties

6. Bardy is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA 98005.

7. Upon information and belief, iRhythm is a corporation organized and existing under the laws of the State of Delaware since September 14, 2006.

8. Upon information and belief, iRhythm has its headquarters and principal place of business at 699 8th Street, Suite 600, San Francisco, California, 94103.

9. According to iRhythm's website, iRhythm is a "digital healthcare company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information."

10. According to iRhythm's 2023 Form 10-K, iRhythm "offer[s] remote cardiac monitoring technology and also function[s] as [a] diagnostic service provider[].".

11. iRhythm and Bardy are and have been competitors in the cardiac or electrocardiogram ("ECG") monitoring field.

Jurisdiction and Venue

12. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. Upon information and belief, as a corporation organized and existing under the laws of the State of Delaware, iRhythm has substantial and continuous contacts with Delaware and has

committed acts of infringement in Delaware sufficient to confer personal jurisdiction over iRhythm.

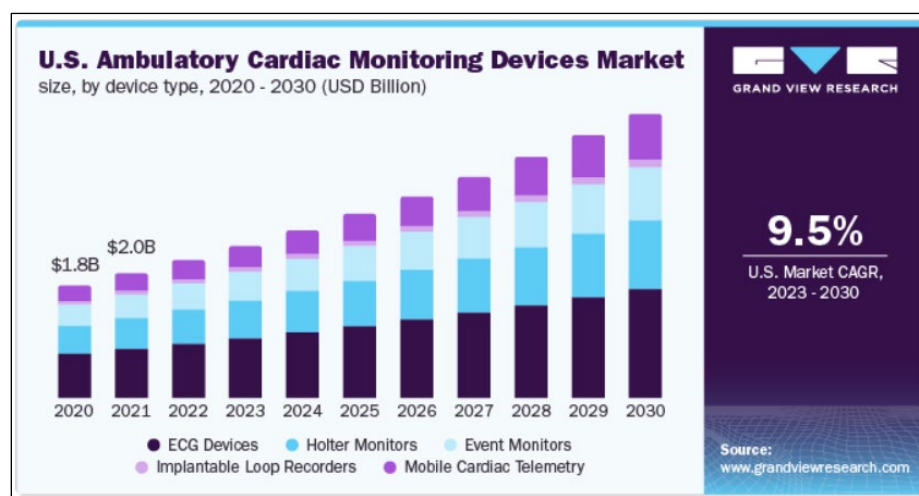
14. Upon information and belief, iRhythm is a commercial entity that makes, uses, advertises, offers for sale, and/or sells heart monitors, including but not limited to ECG monitors and ECG monitoring services. iRhythm currently manufactures, makes, uses, advertises, offers for sale, and/or sells certain ECG monitoring products, including at least the Next-Generation Zio Monitor (the “Zio Monitor”).

15. Upon information and belief, iRhythm makes its Zio line of ECG monitors available to healthcare providers and patients in Delaware.

16. Venue properly lies in this Court under 28 U.S.C. §§ 1391 and 1400(b) because iRhythm, as a Delaware-incorporated corporation, resides in Delaware.

Background and Ambulatory Cardiac Monitoring Devices Market

17. The ambulatory cardiac monitoring devices market can be segmented into Holter monitors, ECG devices, event monitors, mobile cardiac telemetry, and implantable loop recorders. Ex. 3, at 1.



Id.

18. ECG devices accounted for the largest market share of 38.9% in 2022, and the demand for ECG devices is expected to continue to grow due to the increasing incidences of cardiovascular disease and hypertension worldwide, coupled with the ease of access, continuous monitoring, and high accuracy capabilities of the devices. *Id.* at 2. According to a study conducted by the World Health Organization, 17.9 million people die every year due to cardiovascular diseases, which accounts for 32% of the total deaths globally. *Id.*

19. Bardy was founded in 2013 by an electrophysiologist and entrepreneur, Gust H. Bardy, M.D., to overcome common challenges in ambulatory cardiac monitoring. Having witnessed firsthand his late wife's medical challenges, Dr. Bardy sought to elevate the cardiac standard of care by developing a long-term ECG monitor for identifying arrhythmias.

20. Since its founding in 2013, Bardy has been a leading global manufacturer of cardiac monitoring solutions. For example, Bardy manufactures, markets, and sells an industry leading electrocardiography monitor called the Carnation Ambulatory Monitor, or CAMTM Patch (shown below).



21. The CAM™ Patch is widely recognized as the first P-wave centric ECG patch monitor. This innovation was significant because P-wave analysis was traditionally performed using 12-lead ECGs. Although clinically effective, the traditional 12-lead ECG monitor had several drawbacks. Namely, the traditional 12-lead ECG monitor required patients to remain stationary due to the multiple wires or leads connected to electrodes or sensors, with the connected electrodes needing precise placement on the body for accurate readings. As a result, the application and wear of the traditional 12-lead ECG system had to be handled carefully to avoid inaccurate and unusable results.

22. The CAM™ Patch monitor was revolutionary in that it is a P-wave centric ECG wearable monitor designed to be adhered to a patient's chest without physically restricting the patient's mobility during use. The CAM™ Patch monitor is worn on a patient's chest and

continuously records ECG data for up to 14 days. The CAMTM Patch monitor is wearable during sleep, shower, and exercise.

23. Beginning on September 23, 2013, Bardy inventors sought patent protection for these important innovations across a family of patents. This new and innovative body-worn ambulatory ECG monitor allowed physicians and healthcare providers to more effectively and efficiently monitor their patients remotely for longer periods. Not only did the patented inventions improve the quality and amount of data collected, but it also significantly reduced the cost of monitoring patients over long periods of time remotely as opposed to having the patient remain in a clinical setting during the monitoring period.

24. In addition, these patented inventions allowed for reporting of serious cardiac events, such as atrial fibrillation (“AFib”). AFib is an irregular heartbeat, or arrhythmia. It is a serious condition that can lead to blood clots, stroke, heart failure, and other heart-related complications. According to the American Heart Association, over 12 million people are projected to have AFib by 2030.

25. Bardy has numerous U.S. and international patents that cover the innovative CAMTM Patch monitor.

26. In 2021, Bardy was acquired by Hill-Rom Holdings, Inc. (“Hill-Rom”), a leading global medical technology company.

27. In 2017, prior to Hill-Rom’s acquisition of Bardy, Hill-Rom strengthened its focus on diagnostic cardiology and patient monitoring through its acquisition of Mortara Instrument, Inc. (“Mortara”), a leader in the field. Even earlier, in 2015, Hill-Rom acquired another leading global medical technology company, Welch Allyn, Inc. (“Welch Allyn”).

28. The 2021 acquisition of Bardy brings together the innovative research and development teams of Mortara and Welch Allyn with Bardy.

29. Today, Bardy continues to be a leading global manufacturer of physical examination instruments and accessories and electronic medical record connected vital sign and cardiac monitoring solutions through its manufacturing, marketing, and selling of the CAMTM Patch monitor, a leading remote cardiac monitoring solution.

The Asserted Patents

30. Bardy is the assignee of the entire right, title, and interest in numerous United States patents, including the '473 Patent, the '562 Patent, the '261 Patent, and the '735 Patent.

31. The '473 Patent is titled "Electrocardiography Patch" and was duly and legally issued on December 10, 2024, and is assigned to Bardy.

32. The '473 Patent claims, among other things, an electrocardiography monitor patch.

33. The '562 Patent is titled "Electrocardiography Patch" and was duly and legally issued on December 24, 2024, and is assigned to Bardy.

34. The '562 Patent claims, among other things, an electrocardiography monitor patch.

35. The '261 Patent is titled "Moisture-Resistant Electrocardiography Monitor" and was duly and legally issued on April 29, 2025, and is assigned to Bardy.

36. The '261 Patent claims, among other things, an electrocardiography monitor patch.

37. The '735 Patent is titled "Extended Wear Ambulatory Electrocardiography Monitor" and was duly and legally issued on May 27, 2025, and is assigned to Bardy.

38. The '735 Patent claims, among other things, an electrocardiography monitor patch.

iRhythm

39. iRhythm was founded by Uday Kumar in 2006, and currently iRhythm makes, uses, advertises, offers for sale, and/or sells various ECG monitoring products, including the Zio Monitor. *See* Ex. 4.

40. According to iRhythm's website, iRhythm's technology "combin[es] wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, [and] distills data from millions of heartbeats into clinically actionable information."

41. In addition to the Zio Monitor, iRhythm offers two other ECG monitoring products, including the Zio XT Monitor and the Zio AT Monitor.

42. iRhythm's Zio XT Monitor was cleared by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on July 18, 2012. *See* Ex. 5. The Zio XT Monitor was originally called the Zio Patch, but iRhythm rebranded the Zio Patch as the Zio XT Monitor. *Compare id.*, with Ex. 6, at 20.

43. iRhythm's Zio AT Monitor was cleared by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on June 2, 2017. *See* Ex. 7. The Zio AT Monitor was originally called the Zio QX Monitor, but iRhythm rebranded the Zio QX Monitor as the Zio AT Monitor. *Compare id.*, with Ex. 8, at 2/5.

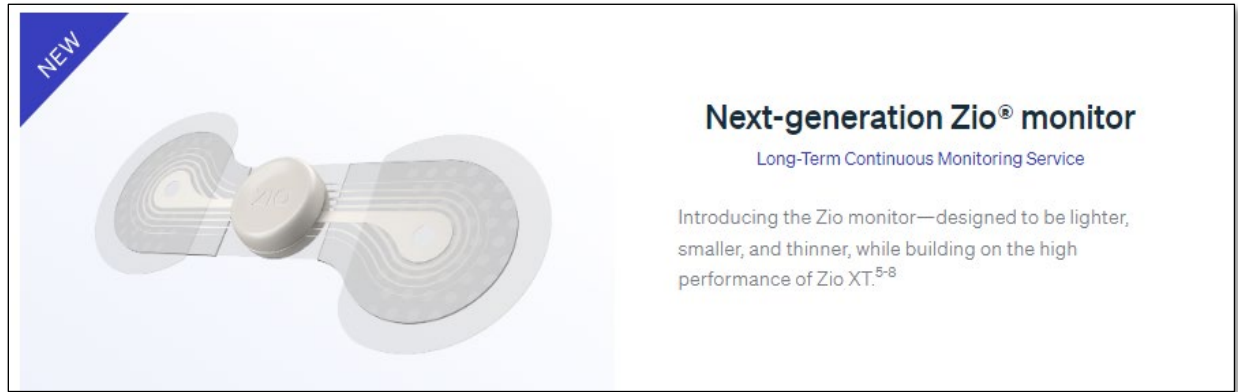
44. iRhythm's Zio Monitor was cleared by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on May 21, 2021. *See* Ex. 8.

iRhythm's Next-Generation Zio Monitor

45. The Zio Monitor (also referred to as the "Next-Generation Zio Monitor") is similar to iRhythm's Zio AT and Zio XT Monitors but has an improved form factor, "which is 23% thinner, 62% lighter, and 72% smaller." Ex. 9, at 2; *see also* Ex. 10. iRhythm's Chief Technology Officer explained that "miniaturization was focused on very clever ways of handling some of the

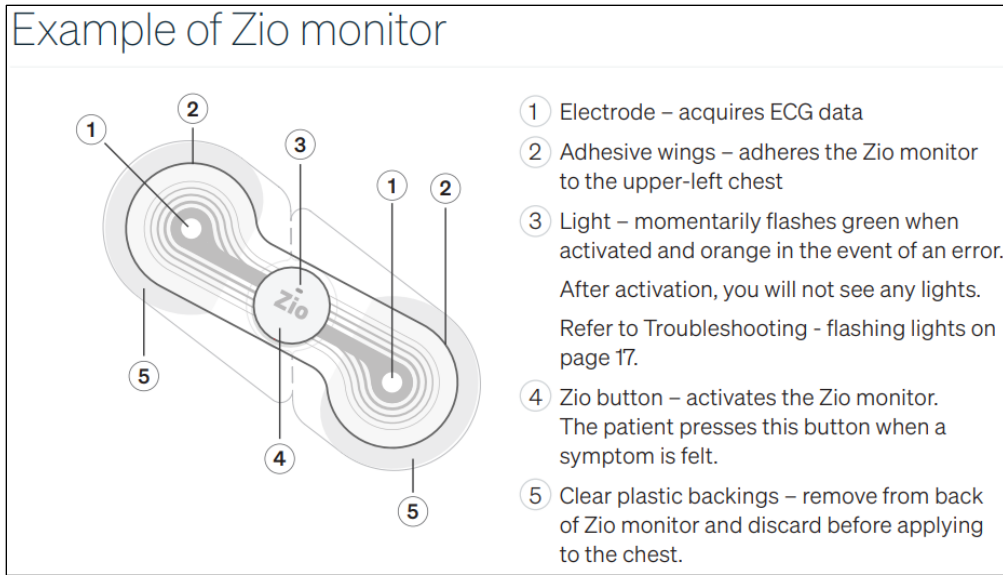
larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing” by “integrat[ing] [the resistors] into the ECG tracings themselves.” Ex. 9, at 3.

46. iRhythm promotes and markets the Zio Monitor on its website. A screenshot of the Zio Monitor from iRhythm’s website is copied below.



Ex. 4.

47. The Zio Monitor includes adhesive portions for adhering to a patient’s chest to “capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring.” Ex. 11, at 21. The electrocardiographic data is acquired by two electrodes provided on each end of the Zio Monitor. *Id.* at 3.



Id.

48. The Zio Monitor senses and records the ECG data continuously for up to 14 days.

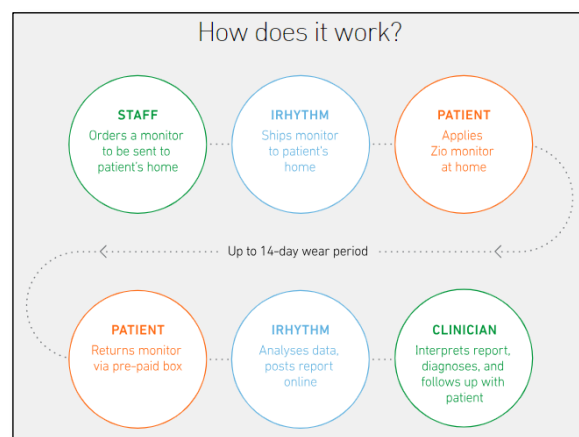
Id. at 6. After conclusion of the wear period (up to 14 days), the patient removes the Zio Monitor and returns it by mail to an iRhythm data processing center. *Id.* at 2. Upon iRhythm's receipt the ECG data is further processed, and a report is generated. *Id.*

49. iRhythm makes the Zio Monitor available to patients directly or through healthcare providers. Ex. 12, at 2.

Home Enrollment patient compliance and performance on par with in-clinic application

	DEVICES APPLIED IN CLINIC	APPLIED BY PATIENTS AT HOME
Mean wear duration (days)	12.5	12.1
Median wear duration (days)	13.8	13.7
Mean analyzable time	95.1%	95.4%
Median analyzable time	98.4%	98.4%
Mean age	75.2	74.3
Median age	74.0	73.0

Data on file. Zio XT monitors prescribed for 14-day wear for age ≥5+ (Zio Database, iRhythm Technologies, 2019)



Id. at 2–3.

50. Upon information and belief, iRhythm manufactures the Zio Monitor in the U.S.

51. iRhythm plans to release its Zio MCT monitor, which “will be on the same form factor that Zio Monitor is on currently. . . . With [Zio] MCT and [Zio] Monitor, they will be the same exact product and manufactured on a single line.” Ex. 13, at 10.

52. iRhythm intends to commercially launch its Zio MCT monitor in 2027 or 2028. *Id.* at 11.

COUNT I

Patent Infringement of U.S. Patent No. 12,161,473

53. Bardy realleges and incorporates by reference the allegations in paragraphs 1–52 of this Second Amended Complaint.

54. iRhythm makes, uses, sells, and/or offers for sale the Zio Monitor in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and, as set forth in the attached non-limiting Claim Chart (Ex. 14), iRhythm directly infringes at least claims 1–3, 6, 8, 10, 13, 15, 16, and 19 of the ’473 Patent, either literally or under the doctrine of equivalents.

55. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from Bardy and during the term of the ’473 Patent.

56. On information and belief, iRhythm has had knowledge of the ’473 Patent since at least December 10, 2024, when Bardy filed its original Complaint alleging infringement of the ’473 Patent. D.I. ¶ 1.

57. On information and belief, despite having knowledge of the ’473 Patent and knowledge that the Zio Monitor infringes at least claims 1–3, 6, 8, 10, 13, 15, 16, and 19 of the ’473 Patent since at least December 10, 2024, iRhythm has continued to make, use, sell, import, and/or offer to sell the Zio Monitor in the United States.

58. iRhythm has willfully infringed the '473 Patent by continuing to make, use, import, offer to sell, and/or sell the Zio Monitor in the United States after having knowledge of the '473 Patent and knowledge that the Zio Monitor infringes at least claims 1–3, 6, 8, 10, 13, 15, 16, and 19 of the '473 Patent.

59. Thus, iRhythm is liable to Bardy in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

60. This case is exceptional under 35 U.S.C. § 285, including due to iRhythm's willful infringement of the '473 Patent.

61. As a result of the acts of infringement by iRhythm, Bardy has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

COUNT II

Patent Infringement of U.S. Patent No. 12,171,562

62. Bardy realleges and incorporates by reference the allegations in paragraphs 1–61 of this Second Amended Complaint.

63. iRhythm makes, uses, sells, and/or offers for sale the Zio Monitor in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and, as set forth in the attached non-limiting Claim Chart (Ex. 15), iRhythm directly infringes at least claims 8–30 of the '562 Patent, either literally or under the doctrine of equivalents.

64. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from Bardy and during the term of the '562 Patent.

65. On information and belief, iRhythm has had knowledge of the '562 Patent since at least December 26, 2024, when Bardy filed its First Amended Complaint alleging infringement of the '562 Patent. D.I. ¶ 9.

66. On information and belief, despite having knowledge of the '562 Patent and knowledge that the Zio Monitor infringes at least claims 8–30 of the '562 Patent since at least December 26, 2024, iRhythm has continued to make, use, sell, import, and/or offer to sell the Zio Monitor in the United States.

67. iRhythm has willfully infringed the '562 Patent by continuing to make, use, import, offer to sell, and/or sell the Zio Monitor in the United States after having knowledge of the '562 Patent and knowledge that the Zio Monitor infringes at least claims 8–30 of the '562 Patent.

68. Thus, iRhythm is liable to Bardy in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

69. This case is exceptional under 35 U.S.C. § 285, including due to iRhythm's willful infringement of the '562 Patent.

70. As a result of the acts of infringement by iRhythm, Bardy has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

COUNT III

Patent Infringement of U.S. Patent No. 12,285,261

71. Bardy realleges and incorporates by reference the allegations in paragraphs 1–70 of this Second Amended Complaint.

72. iRhythm makes, uses, sells, and/or offers for sale the Zio Monitor in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and, as set forth in the attached non-limiting Claim Chart (Ex. 18), iRhythm directly infringes at least claim 1 of the '261 Patent, either literally or under the doctrine of equivalents.

73. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from Bardy and during the term of the '261 Patent.

74. On information and belief, iRhythm has had knowledge of the '261 Patent since at least May 28, 2025, when Bardy's counsel sent a letter to iRhythm's counsel identifying the '261 Patent.

75. On information and belief, despite having knowledge of the '261 Patent and knowledge that the Zio Monitor infringes at least claim 1 of the '261 Patent since at least May 28, 2025, iRhythm has continued to make, use, sell, import, and/or offer to sell the Zio Monitor in the United States.

76. iRhythm has willfully infringed the '261 Patent by continuing to make, use, import, offer to sell, and/or sell the Zio Monitor in the United States after having knowledge of the '261 Patent and knowledge that the Zio Monitor infringes at least claim 1 of the '261 Patent.

77. Thus, iRhythm is liable to Bardy in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

78. This case is exceptional under 35 U.S.C. § 285, including due to iRhythm's willful infringement of the '261 Patent.

79. As a result of the acts of infringement by iRhythm, Bardy has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

COUNT IV

Patent Infringement of U.S. Patent No. 12,310,735

80. Bardy realleges and incorporates by reference the allegations in paragraphs 1–79 of this Second Amended Complaint.

81. iRhythm makes, uses, sells, and/or offers for sale the Zio Monitor in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and,

as set forth in the attached non-limiting Claim Chart (Ex. 19), iRhythm directly infringes at least claim 1 of the '735 Patent, either literally or under the doctrine of equivalents.

82. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from Bardy and during the term of the '735 Patent.

83. On information and belief, iRhythm has had knowledge of the '735 Patent since at least May 28, 2025, when Bardy's counsel sent a letter to iRhythm's counsel identifying the '735 Patent.

84. On information and belief, despite having knowledge of the '735 Patent and knowledge that the Zio Monitor infringes at least claim 1 of the '735 Patent since at least May 28, 2025, iRhythm has continued to make, use, sell, import, and/or offer to sell the Zio Monitor in the United States.

85. iRhythm has willfully infringed the '735 Patent by continuing to make, use, import, offer to sell, and/or sell the Zio Monitor in the United States after having knowledge of the '735 Patent and knowledge that the Zio Monitor infringes at least claim 1 of the '735 Patent.

86. Thus, iRhythm is liable to Bardy in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

87. This case is exceptional under 35 U.S.C. § 285, including due to iRhythm's willful infringement of the '735 Patent.

88. As a result of the acts of infringement by iRhythm, Bardy has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

RELIEF REQUESTED

WHEREFORE, Bardy requests that the Court enter a judgment in its favor and against iRhythm and provide Bardy the following relief:

- A. Order, adjudge, and decree that iRhythm has infringed the Asserted Patents;
- B. Order, adjudge, and decree that iRhythm's infringement of the Asserted Patents is exceptional under 35 U.S.C. § 285;
- C. Order, adjudge, and decree that iRhythm's infringement of the Asserted Patents has been willful;
- D. Award Bardy damages for patent infringement including prejudgment interest and costs against iRhythm under 35 U.S.C. §§ 284 and 289;
- E. Award Bardy up to three times its damages to compensate Bardy under 35 U.S.C. § 284;
- F. Award Bardy its reasonable attorneys' fees under 35 U.S.C. § 285; and
- G. Award such other and further relief as the Court may deem just including but not limited to an accounting for acts of infringement made but not otherwise awarded to Bardy.

JURY DEMAND

Bardy demands trial by jury on all issues presented in this complaint.

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